

Quality Assurance Surveillance Plan (QASP)

Performance Requirements Summary

The Contractor's performance will be evaluated on a semiannual basis through the use of a Quality Assurance Surveillance Plan (QASP). This section provides a summary on the performance measures used by the Government. The specific activity, acceptable quality level, method and frequency of surveillance, incentives, and fees that the Contractor will be measured on are contained in the QASP document. The QASP may be revised based upon review by the Project Officers so the measures are current to the work conducted by the Contractor. The QASP is broken into four major sections:

1. Quality
2. Timeliness
3. File storage
4. QA activities

Quality

The Contractor will be evaluated on overall quality of protocol development support services through the use of survey forms and evaluations of abstracted elements in PATS for LOIs, Concepts, Initial submission protocols, Revisions, and Amendments.

Timeliness

The Contractor will be evaluated on the timeliness of tasks performed such as acknowledgement, abstraction, distribution and routing mailings, and development of TAC/TADs.

File Storage

The Contractor will be evaluated on how well the protocol files are stored and maintained. The Contractor will be evaluated on the accessibility of protocol files on-site at PIO, the percentage of protocols electronically linked to PATS, and the ability to recover files from the resource center.

Quality Assurance Activities

The Contractor will be evaluated on the strength of its QA activities. The Contractor will be evaluated on the quality and scores received on internal and external satisfaction surveys, training programs, typing requests, and cost control.

Quality Assurance Surveillance Plan

QUALITY ASSURANCE SURVEILLANCE PLAN (QASP) QUARTERLY REPORT FOR THE PIO SUPPORT CONTRACT, Contract # XXXXXXXX

Performance Period: DD/MM/YYYY - DD/MM/YYYY

Description										Fee Adjustment	
Performance Indicators		Purpose	Method of Surveillance	Frequency	Acceptable Quality Level	Incentives	Disincentives	Base Fee for task	Max Fee for Task	Quarterly Score	Fee Awarded
1	Quality: New Protocol Submissions	The Contractor shall abstract document-related keywords and milestones into the CTEP-ESYS to assist with Program decision making.	Random semiannual sampling of appropriate protocols	Semiannual	Year 1= 95%, Year 2 = 96%, Year 3+ = 97%	See Table #1 in the SOW.	See Table #1 in the SOW.	5%	6%		
2	Quality: LOIs and Concepts	The Contractor shall abstract document-related keywords and milestones into the CTEP-ESYS to assist with Program decision making.	Random semiannual sampling of appropriate LOIs and Concepts	Semiannual	Year 1= 95%, Year 2 = 96%, Year 3+ = 97%	See Table #1 in the SOW.	See Table #1 in the SOW.	5%	6%		
3	Quality: Approved Protocols	The Contractor shall abstract document-related keywords and milestones into the CTEP-ESYS to assist with Program decision making.	Random semiannual sampling of appropriate protocols	Semiannual	Year 1= 95%, Year 2 = 96%, Year 3+ = 97%	See Table #2 in the SOW.	See Table #2 in the SOW.	8%	9%		
4	Quality: Protocol Amendments	The Contractor shall abstract document-related keywords and milestones into the CTEP-ESYS to assist with Program decision making.	Random semiannual sampling of appropriate protocols	Semiannual	Year 1= 95%, Year 2 = 96%, Year 3+ = 97%	See Table #2 in the SOW.	See Table #2 in the SOW.	8%	9%		

Description									Fee Adjustment	
Performance Indicators	Purpose	Method of Surveillance	Frequency	Acceptable Quality Level	Incentives	Disincentives	Base Fee for task	Max Fee for Task	Quarterly Score	Fee Awarded
5	Quality: Protocol and Amendment Coding	The Contractor shall provide accurate and complete treatment assignment codes and descriptors, subgroup descriptions and embedded correlative study descriptions as required by current CTEP business rules to increase the efficiency and integrity of electronic submission of data.	Random semiannual sampling of appropriate protocols	Semiannual	18 of 20 selected documents shall have accurate codes and descriptors abstracted.	Increase fee 1% for each document over 18 that has accurate codes and descriptors.	Decrease fee 1% for each document that has missing or inaccurate codes/descriptors.	3%	5%	
6	Quality: Scientific Writing Support	The Contractor shall provide administrative scientific writing support to assist CTEP Staff with protocol-related correspondence.	Semiannual review of all Central Typing Request Forms submitted by CTEP staff.	Semiannual	An average semiannual score of 80-90% on the Central Typing Request Forms filled out by CTEP requestors.	Increase fee 1% if average satisfaction score is greater than 90%.	Decrease fee 1% if AQL is not met.	1%	2%	
7	Timeliness: LOI Abstraction Process	The effectiveness of the Contractor to streamline the LOI abstraction process will be measured to assist in streamlining the protocol development process and assist CTEP with the review and decision making process.	Measured by generating and reviewing a semiannual report	Semiannual	All LOIs shall be abstracted within five business days of receipt.	Increase fee 1% for abstraction time less than two business days of receipt.	Decrease fee 1% if AQL is not met.	2%	4%	

Description									Fee Adjustment	
Performance Indicators	Purpose	Method of Surveillance	Frequency	Acceptable Quality Level	Incentives	Disincentives	Base Fee for task	Max Fee for Task	Quarterly Score	Fee Awarded
8	Timeliness: PTMA Abstraction Process	The effectiveness of the Contractor to streamline the PTMA abstraction process will be measured to assist in streamlining the protocol development process and assist CTEP with the review and decision making process.	Measured by generating and reviewing a semiannual report and comparing it to the PTMA Solicitation tracking log	Semiannual	Average abstraction time will be four business days of due date as stated in PTMA solicitation for solicitation response of <100 PTMAs; five business days of due date for solicitation response of >= 100 PTMAs.	none	Decrease fee 1% if AQL is not met.	1%	1%	
9	Timeliness: Abstraction of New Protocols and New Concepts	The effectiveness of the Contractor to streamline the new protocol and new concept abstraction process will be measured to assist in streamlining the protocol development process and assist CTEP with the review and decision making process.	Measured by generating and reviewing a semiannual report	Semiannual	All documents received between Wednesday of week one and COB Tuesday of week two shall be abstracted before Friday 12:00pm of week two.	none	Decrease fee 1% if AQL is not met.	2%	2%	

Description										Fee Adjustment	
Performance Indicators		Purpose	Method of Surveillance	Frequency	Acceptable Quality Level	Incentives	Disincentives	Base Fee for task	Max Fee for Task	Quarterly Score	Fee Awarded
10	Timeliness: Amendment to 1st Reviewer	The effectiveness of the Contractor to streamline the amendment review process will be measured to assist in streamlining the protocol development process and assist CTEP with the review and decision making process.	Measured by generating and reviewing a semiannual report	Semiannual	The semiannual average of amendment processing time from receipt to first reviewer shall be two calendar days.	none	Decrease fee 5% if AQL is not met.	5%	5%		
11	Timeliness: Amendment Review Process	The effectiveness of the Contractor to streamline the amendment review process will be measured to assist in streamlining the protocol development process and assist CTEP with the review and decision making process.	Measured by generating and reviewing a semiannual report	Semiannual	Year 1 = 7 days; Year 2 = 6 days; Year 3+ = 5 days	See Table #3 in the SOW.	See Table #3 in the SOW.	7%	10%		
12	Timeliness: Approved Protocol Coding	The effectiveness of the Contractor to prepare and distribute accurate and complete protocol coding letters will be measured to assist in streamlining the protocol development process.	Measured by generating and reviewing a semiannual report	Semiannual	The Contractor shall provide accurate codes and descriptors for protocols and amendments within four business days of approval.	none	Decrease fee 1% if AQL is not met.	2%	2%		

Description									Fee Adjustment	
Performance Indicators	Purpose	Method of Surveillance	Frequency	Acceptable Quality Level	Incentives	Disincentives	Base Fee for task	Max Fee for Task	Quarterly Score	Fee Awarded
13	Timeliness: Amendment Coding	The effectiveness of the Contractor to prepare and distribute accurate and complete protocol coding letters will be measured to assist in streamlining the protocol development process.	Measured by generating and reviewing a semiannual report	Semiannual	The Contractor shall provide accurate codes and descriptors for protocols and amendments within four business days of approval.	none	Decrease fee 2% if AQL is not met.	2%	2%	
14	Timeliness: PTMA Solicitation Mailings	The effectiveness of the Contractor to rapidly disseminate PTMA mailings will be assessed.	Measured by reviewing the PTMA Solicitation tracking log semiannually	Semiannual	All PTMA solicitations shall be sent within 1 business day or less of receipt of final solicitation.	none	Decrease fee 1% if AQL is not met.	1%	2%	
15	Timeliness: Revision Review Process	The effectiveness of the Contractor to streamline the revision review process will be measured to assist in streamlining the protocol development process and assist CTEP with the review and decision making process.	Measured by generating and reviewing a semiannual report	Semiannual	Year 1 = 12 days; Year 2 = 10 days; Year 3+ = 9 days	See Table #4 in the SOW.	See Table #4 in the SOW.	3%	5%	
16	Timeliness: Support for Routine CTEP Mailings	The effectiveness of the Contractor to rapidly disseminate CTEP mailings will be measured.	Measured by reviewing the tracking log semiannually	Semiannual	All IND-related mailings shall be sent out within five business days or less of receipt of complete document.	none	Decrease fee 1% if AQL is not met.	1%	1%	

Description									Fee Adjustment	
Performance Indicators	Purpose	Method of Surveillance	Frequency	Acceptable Quality Level	Incentives	Disincentives	Base Fee for task	Max Fee for Task	Quarterly Score	Fee Awarded
17	Timeliness: Support for Priority CTEP Mailings	The effectiveness of the Contractor to rapidly disseminate priority CTEP mailings will be measured.	Measured by reviewing the tracking log	Semiannual	All priority mailings shall be sent out within two business days or less of receipt of complete document.	Increase fee 1% if average time is one day or less.	Decrease fee 1% if average time is three calendar days. Decrease fee 2% if average time is four or more calendar days.	2%	3%	
18	Timeliness: Scientific Writing Support	The effectiveness of the Contractor to efficiently provide administrative support to assist CTEP Staff with protocol-related correspondence will be measured.	Semiannual review of all Document Approval Forms submitted by CTEP staff.	Semiannual	Semiannual average time from receipt to return of document to CTEP requestor is two business days or less.	Increase fee 1% if average time from receipt of request in PIO to return to requestor is less than two business days.	Decrease fee 1% if time from receipt of request in PIO to return to requestor is greater than three business days.	2%	3%	
19	Timeliness: Amendment Submission to RAB	The effectiveness of the Contractor to send protocol documents to Regulatory Affairs Branch for submission to the FDA will be measured.	Measured by generating and reviewing a semiannual report	Semiannual	Average time from Document Approval to RAB receipt for FDA processing will be 30 calendar days or less.	Increase fee 1% if average time is 15 calendar days or less.	Decrease fee 1% if AQL is not met.	2%	3%	
20	File Storage: Electronic Storage	To assure rapid access by CTEP staff and contractors to documents.	Measured by generating and reviewing a semiannual report	Semiannual	96% of complete documents saved electronically and linked to the PIO database	Increase fee 1% if greater than or equal to 98%.	Decrease fee 1% for each 2% drop below AQL.	2%	3%	

Description										Fee Adjustment	
Performance Indicators		Purpose	Method of Surveillance	Frequency	Acceptable Quality Level	Incentives	Disincentives	Base Fee for task	Max Fee for Task	Quarterly Score	Fee Awarded
					(currently named PATS)						
21	Timeliness: Consensus Review Compilation	To assure the effectiveness of the Contractor to compile consensus reviews efficiently.	Random semiannual sampling of appropriate protocols	Semiannual	Average time from PRC to lead reviewer is 3 business days or less	Increase fee if less than 2 days	Decrease fee 1% if AQL is not met.	1%	2%		
22	Quality: Internal Survey	The Contractor shall assess overall quality of customer (CTEP staff) satisfaction.	The COR will review the QA survey.	annual	Average score of greater than or equal to 80%-90% on the QA survey.	Increase fee 2% if average score is greater than or equal to 90%.	Decrease fee 2% for an average score of 70% to 79%. The Contractor will lose entire fee if average score is less than 70%.	4%	6%		
23	Quality: External Survey	The Contractor shall assess overall quality of customer (non-CTEP staff) satisfaction.	The COR will review the QA survey.	annual	Average score of greater than or equal to 80%-90% on the QA survey.	Increase fee 2% if average score is greater than or equal to 90%.	Decrease fee 1.5% for an average score of 70% to 79%. The Contractor will lose entire fee if average score is less than 70%.	3%	5%		
24	Trainings: Quantity	The Contractor shall develop PIO related training programs for CTEP and/or extramural staff and contractors to assist CTEP Staff and extramural staff in the protocol development and review process.	Semiannual review of the training program log.	Semiannual	The Contractor shall develop and provide four PIO-related training programs per year on a quarterly basis.	none	Decrease fee 1% for every training program not provided.	2%	2%		
25	Trainings: Quality	The Contractor shall develop PIO related training programs for CTEP and/or extramural staff and contractors to assist CTEP Staff and extramural	Semiannual review of the QA surveys for each training	Semiannual	Average score of greater than or equal to 80%-90% on	Increase fee 1% if average score is greater	Decrease fee 0.5% for an average score of 70% to 79%. The Contractor will	1%	2%		

Description									Fee Adjustment	
Performance Indicators	Purpose	Method of Surveillance	Frequency	Acceptable Quality Level	Incentives	Disincentives	Base Fee for task	Max Fee for Task	Quarterly Score	Fee Awarded
	staff in the protocol development and review process.	session		the QA survey.	than or equal to 90% for all training programs combined.	lose entire fee if average score is less than 70%.				

1. Quality: New Protocol Submissions

Purpose: The Contractor shall abstract document-related keywords and milestones into the CTEP-ESYS to assist with Program decision making.

Element: Quality

AQL: Year 1= 95%, Year 2 = 96%, Year 3+ = 97%

Incentives: See Table #1.

Disincentives: See Table #1.

Method: Random semiannual sampling of appropriate protocols

Timing: On or about the 15th of the month following the half year reviewed.

Exceptions: non-CTEP protocols

Fee:

Base: 5%

Max: 6%

Business Rules:

Document Selection: The government will generate a list of new protocols received and abstracted during the period of review into an excel spreadsheet. The government will run a random number list in excel and the first 20 random numbers (and their corresponding protocols) will be selected.

Field Selection: The COR will select ten fields to be checked each quarter; eight of which will be from the “Major Fields” list

and two from the “Minor Fields” list. The fields will be selected prior to selecting the documents to avoid any bias.

Major fields to be checked for new protocols:

Title
 Study phase
 Principal Investigator
 PI e-mail
 Lead Organization
 Study disease(s)
 Study agent(s)
 IND #
 Investigational or commercial agent
 PMB distribution
 NIH Sponsor
 Treatment study (Y/N)
 Receipt date

Minor Fields:

Document #
 Local protocol #
 NCI Trial Owner
 LOI # or Concept # linked to protocol
 Accrual: minimum
 Accrual: maximum
 Accrual: rate

Table #1

		Percent of fields found accurate and complete										
	Contract year	≤90%	91%	92%	93%	94%	95%	96%	97%	98%	99%	100%
Fee	1	0%	1%	2%	3%	4%	5%	6%	6%	6%	6%	6%

	2	0%	0%	1%	2%	3%	4%	5%	6%	6%	6%	6%
	3+	0%	0%	0%	1%	2%	3%	4%	5%	6%	6%	6%

2. Quality: LOIs and Concepts

Purpose: The Contractor shall abstract document-related keywords and milestones into the CTEP-ESYS to assist with Program decision making.

Element: Quality

AQL: Year 1= 95%, Year 2 = 96%, Year 3+ = 97%

Incentives: See Table #1.

Disincentives: See Table #1.

Method: Random semiannual sampling of appropriate LOIs and Concepts

Timing: On or about the 15th of the month following the half year reviewed.

Exceptions: non-CTEP LOIs and Concepts

Fee:

Base: 5%

Max: 6%

Business Rules:

Document Selection: The government will generate a list of new LOIs and Concepts received and abstracted during the period of review into an excel spreadsheet. The government will run a random number list in excel and the first 20 random numbers (and their corresponding protocols) will be selected

Field Selection: The COR will select ten fields to be checked each quarter; eight of which will be from the “Major Fields” list and two from the “Minor Fields” list. The fields will be selected prior to selecting the documents to avoid any bias.

Major fields to be checked for new LOIs and concepts:

Title

Study phase

Principal Investigator

PI e-mail

Lead Organization
 Study disease(s)
 Study agent(s)
 Investigational or commercial agent
 NIH Sponsor
 Treatment study (Y/N)
 Receipt date

Minor Fields:

Document #
 Accrual: minimum
 Accrual: maximum
 Accrual: rate
 CRDL

Table #1

Percent of fields found accurate and complete

	Contract year	≤90%	91%	92%	93%	94%	95%	96%	97%	98%	99%	100%
Fee	1	0%	1%	2%	3%	4%	5%	6%	6%	6%	6%	6%
	2	0%	0%	1%	2%	3%	4%	5%	6%	6%	6%	6%
	3+	0%	0%	0%	1%	2%	3%	4%	5%	6%	6%	6%

3. Quality: Approved Protocols

Purpose: The Contractor shall abstract document-related keywords and milestones into the CTEP-ESYS to assist with Program decision making.

Element: Quality

AQL: Year 1= 95%, Year 2 = 96%, Year 3+ = 97%

Incentives: See Table #2.

Disincentives: See Table #2.

Method: Random semiannual sampling of appropriate protocols

Timing: On or about the 15th of the month following the half year reviewed.

Exceptions: non-CTEP studies

Fee:

Base: 8%

Max: 9%

Business Rules:

Document Selection: The government will generate a list of protocols approved during the period of review into an excel spreadsheet. The government will run a random number list in excel and the first 20 random numbers (and their corresponding protocols) will be selected.

Field Selection: The COR will select five fields to be checked each quarter. The fields will be selected prior to selecting the documents to avoid any bias.

Fields to be checked for approved protocols

Version date

Title

Disease(s)

Agent(s)

Investigational or commercial agent

Monitoring method correctly assigned

AE table correctly assigned

Milestone: Approval Letter Sent to Investigator

Milestone: PMB Approval Received

Milestone: Distribution of approved document: TRI, EMMES, CTRO, CTMS

Table #2

Percent of fields found accurate and complete

	Contract year	≤88%	89%	90%	91%	91%	92%	93%	94%	95%	96%	97%	98%	99%	100%
Fee	1	0%	1%	2%	3%	4%	5%	6%	7%	8%	8%	9%	9%	9%	9%

	2	0%	0%	1%	2%	3%	4%	5%	6%	7%	8%	8%	9%	9%	9%
	3+	0%	0%	0%	1%	2%	3%	4%	5%	6%	7%	8%	8%	9%	9%

4. Quality: Protocol Amendments

Purpose: The Contractor shall abstract document-related keywords and milestones into the CTEP-ESYS to assist with Program decision making.

Element: Quality

AQL: Year 1= 95%, Year 2 = 96%, Year 3+ = 97%

Incentives: See Table #2.

Disincentives: See Table #2.

Method: Random semiannual sampling of appropriate protocols

Timing: On or about the 15th of the month following the half year reviewed.

Exceptions: non-CTEP protocols

Fee:

Base: 8%

Max: 9%

Business Rules:

Document Selection: The government will generate the list of amendments with Approval/Disapproval abstracted into an excel spreadsheet. The government will run a random number list in excel and the first 20 random numbers (and their corresponding protocols) will be selected.

Field Selection: The Project Officer will select five fields to be checked each quarter. The fields will be selected prior to selecting the documents to avoid any bias.

Fields to be checked for approved amendments

Receipt date

Version date

Change reason(s) entered correctly

Approval on Hold/Document Sent to CIRB (when appropriate)

Anticipated Primary Completion Date
Milestone: CTEP Coordinator Signed
Milestone: Approval/Disapproval letter sent to investigator
Milestone: Distribution of Approved Document: TRI, EMMES, PDQ, CTMS

Table #2

		Percent of fields found accurate and complete													
	Contract year	≤88%	89%	90%	91%	91%	92%	93%	94%	95%	96%	97%	98%	99%	100%
Fee	1	0%	1%	2%	3%	4%	5%	6%	7%	8%	8%	9%	9%	9%	9%
	2	0%	0%	1%	2%	3%	4%	5%	6%	7%	8%	8%	9%	9%	9%
	3+	0%	0%	0%	1%	2%	3%	4%	5%	6%	7%	8%	8%	9%	9%

5. Quality: Protocol and Amendment Coding

Purpose: The Contractor shall provide accurate and complete treatment assignment codes and descriptors and subgroup descriptions as required by current CTEP business rules to increase the efficiency and integrity of electronic submission of data.

Element: Quality

AQL: 18 of 20 selected documents shall have accurate codes and descriptors abstracted.

Incentives: Increase fee 1% for each document over 18 that has accurate codes and descriptors.

Disincentives: Decrease fee 1% for each document that has missing or inaccurate codes/descriptors.

Method: Random semiannual sampling of appropriate protocols

Timing: On or about the 15th of the month following the half year reviewed.

Exceptions: non-CTEP protocols

Fee:

Base: 3%

Max: 5%

Business Rules:

Document Selection: The government will compile a list of all reviewed coding letters in an excel spreadsheet. The government will run a random number list in excel and the first 20 random numbers (and their corresponding protocols) will be selected.

6. Quality: Scientific Writing Support

Purpose: The Contractor shall provide administrative scientific writing support to assist CTEP Staff with protocol-related correspondence.

Element: Quality

AQL: An average semiannual score of 80-90% on the Central Typing Request Forms filled out by CTEP requestors.

Incentives: Increase fee 1% if average satisfaction score is greater than 90%.

Disincentives: Decrease fee 1% if AQL is not met.

Method: Quarterly review of all Central Typing Request Forms submitted by CTEP staff.

Timing: On or about the 15th of the month following the half year reviewed.

Exceptions: none

Fee:

Base: 1%

Max: 2%

Business Rules:

The Contractor shall maintain a Document Tracking Log which shall include (at minimum) the following information for each request: CTEP requestor, date request received in PIO, date completed, cumulative score. Each writing request will count as one request, even if it has several iterations.

7. Timeliness: LOI Abstraction Process

Purpose: The effectiveness of the Contractor to streamline the LOI abstraction process will be measured to assist in streamlining the protocol development process and assist CTEP with the review and decision making process.

Element: Timeliness

AQL: All LOIs shall be abstracted within five business days of receipt.

Incentives: Increase fee 2% for abstraction time less than two business days of receipt.

Disincentives: Decrease fee 2% if AQL is not met.

Method: Measured by generating and reviewing a semiannual report

Timing: On or about the 15th of the month following the half year reviewed.

Exceptions: non-CTEP LOIs

Fee:

Base: 2%

Max: 4%

Business Rules: None

8. Timeliness: Project Team Member Application (PTMA) Abstraction Process

Purpose: The effectiveness of the Contractor to streamline the PTMA abstraction process will be measured to assist in streamlining the protocol development process and assist CTEP with the review and decision making process.

Element: Timeliness

AQL: Average abstraction time will be four business days of due date as stated in PTMA Solicitation for solicitation response of <100 PTMAs; five business days of due date for solicitation response of >= 100 PTMAs.

Incentives: none

Disincentives: Decrease fee 1% if AQL is not met.

Method: Measured by generating and reviewing a semiannual report and comparing it to the PTMA tracking log

Timing: On or about the 15th of the month following the half year reviewed.

Exceptions: none

Fee:

Base: 1%

Max: 1%

Business Rules:

Base fee will be awarded when there are no PTMA solicitations in the period being reviewed.

9. Timeliness: Abstraction of New Protocols and New Concepts

Purpose: The effectiveness of the Contractor to streamline the new protocol and new concept abstraction process will be measured to assist in streamlining the protocol development process and assist CTEP with the review and decision making process.

Element: Timeliness

AQL: All documents received between Wednesday of week one and COB Tuesday of week two shall be abstracted before Friday 12:00pm of week two.

Incentives: none

Disincentives: Decrease fee 1% if AQL is not met.

Method: Measured by generating and reviewing a semiannual report

Timing: On or about the 15th of the month following the half year reviewed.

Exceptions: non-CTEP protocols and concepts

Fee:

Base: 2%

Max: 2%

Business Rules: None

10. Timeliness: Amendment to 1st Reviewer

Purpose: The effectiveness of the Contractor to streamline the amendment review process will be measured to assist in streamlining the protocol development process and assist CTEP with the review and decision making process.

Element: Timeliness

AQL: The semiannual average of amendment processing time from receipt to first reviewer shall be two calendar days.

Incentives: none

Disincentives: Decrease fee 5% if AQL is not met.

Method: Measured by generating and reviewing a semiannual report

Timing: On or about the 15th of the month following the half year reviewed.

Exceptions: non-CTEP protocols

Fee:

Base: 5%

Max: 5%

Business Rules:

The amendment processing time will be defined as the number of calendar days from the date of receipt of the amendment in PIO to the date the amendment is sent to the 1st reviewer minus on hold time for incomplete documents, clinical hold, or other “on hold” reasons that would prohibit the routing of the document. The day of receipt will be day “0” for counting processing time.

11. Timeliness: Amendment Review Process

Purpose: The effectiveness of the Contractor to streamline the amendment review process will be measured to assist in streamlining the protocol development process and assist CTEP with the review and decision making process.

Element: Timeliness

AQL: Year 1 = 7 days; Year 2 = 6 days; Year 3+ = 5 days

Incentives: See Table #3.

Disincentives: See Table #3.

Method: Measured by generating and reviewing a semiannual report

Timing: On or about the 15th of the month following the half year reviewed.

Exceptions: non-CTEP protocols and time when document is ‘on-hold’ and not routing

Fee:

Base: 7%

Max: 10%

Business Rules:

The amendment processing time will be defined as the number of calendar days from the date of receipt of the amendment in PIO to the date the approval/disapproval letter is sent to the investigator minus on hold time for incomplete documents, clinical hold, or other “on hold” reasons that would prohibit the routing of the document. The day of receipt will be day “0” for counting processing time. The AQL becomes more stringent over time.

Table #3

Calendar days to process amendments

	Contract year	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Fee	1	10%	10%	10%	10%	9%	8%	7%	6%	5%	4%	3%	2%	1%	0%

	2	10%	10%	10%	9%	8%	7%	6%	5%	4%	3%	2%	1%	0%	0%
	3+	10%	10%	9%	8%	7%	6%	5%	4%	3%	2%	1%	0%	0%	0%

12. Timeliness: Approved Protocol Coding

Purpose: The effectiveness of the Contractor to prepare and distribute accurate and complete protocol coding letters will be measured to assist in streamlining the protocol development process.

Element: Timeliness

AQL: The Contractor shall provide accurate codes and descriptors for protocols and amendments within four business days of approval.

Incentives: none

Disincentives: Decrease fee 2% if AQL is not met.

Method: Measured by generating and reviewing a semiannual report

Timing: On or about the 15th of the month following the half year reviewed.

Exceptions: non-CTEP protocols

Fee:

Base: 2%

Max: 2%

Business Rules: None

13. Timeliness: Amendment Coding

Purpose: The effectiveness of the Contractor to prepare and distribute accurate and complete protocol coding letters will be measured to assist in streamlining the protocol development process.

Element: Timeliness

AQL: The Contractor shall provide accurate codes and descriptors for protocols and amendments within four business days of approval.

Incentives: none

Disincentives: Decrease fee 2% if AQL is not met.

Method: Measured by generating and reviewing a semiannual report

Timing: On or about the 15th of the month following the half year reviewed.

Exceptions: non-CTEP protocols

Fee:

Base: 2%

Max: 2%

Business Rules: None

14. Timeliness: Project Team Member Application Solicitation Mailings

Purpose: The effectiveness of the Contractor to rapidly disseminate PTMA solicitation mailings will be assessed.

Element: Timeliness

AQL: All PTMA solicitations shall be sent within the next business day or less of receipt of final solicitation and distribution list.

Incentives: none

Disincentives: Decrease fee 1% if AQL is not met.

Method: Measured by reviewing the PTMA solicitation tracking log semiannually

Timing: On or about the 15th of the month following the half year reviewed.

Exceptions: none

Fee:

Base: 1%

Max: 2%

Business Rules:

The Contractor shall maintain a PTMA Solicitation Tracking Log which shall include (at minimum) the following information for each PTMA solicitation: CTEP requestor, date request received in PIO and date sent. Base fee will be awarded when there are no PTMA solicitations in the period being reviewed.

15. Timeliness: Revision Review Process

Purpose: The effectiveness of the Contractor to streamline the revision review process and assist CTEP with the review and decision making process.

Element: Timeliness

AQL: Year 1 = N/A; Year 2 = N/A; Year 3+ = 10 days

Incentives: See Table #4.

Disincentives: See Table #4.

Method: Measured by generating and reviewing a semiannual report

Timing: On or about the 15th of the month following the half year reviewed.

Exceptions: non-CTEP protocols and time when document is ‘on-hold’ and not routing

Fee:

Base: 3%

Max: 5%

Business Rules:

The amendment processing time will be defined as the number of calendar days from the date of receipt of the revision in PIO to the date the approval/disapproval letter is sent to the investigator minus on hold time for incomplete documents, clinical hold, or other “on hold” reasons that would prohibit the routing of the document. The day of receipt will be day “0” for counting processing time. The AQL becomes more stringent over time.

Table #4

Calendar days to process revisions

	Contract year	1-6	7	8	9	10	11	12	13	14
Fee	1	5%	5%	5%	5%	4%	4%	3%	2%	0%
	2	5%	5%	5%	4%	3%	3%	2%	1%	0%
	3+	5%	5%	4%	3%	3%	2%	1%	0%	0%

16. Timeliness: Support for Routine CTEP Mailings

Purpose: The effectiveness of the Contractor to rapidly disseminate CTEP mailings will be assessed.

Element: Timeliness

AQL: All routine mailings shall be sent out within fourteen calendar days or less.

Incentives: Increase fee 1% if average time is seven calendar days or less.

Disincentives: Decrease fee 1% if average time is 15 to 21 calendar days. Decrease fee 2% if average time is 22 or more calendar days.

Method: Measured by reviewing the tracking log semiannually

Timing: On or about the 15th of the month following the half year reviewed.

Exceptions: none

Fee:

Base: 2%

Max: 3%

Business Rules:

Routine mailing definition: mailings that do not require a protocol or status change and are not considered a priority by CTEP. The Contractor shall maintain a Routine Mailing Tracking Log which shall include (at minimum) the following information for each routine mailing: Agent or protocol number, mailing type, date request received in PIO, date sent and number of protocols affected.

17. Timeliness: Support for Priority CTEP Mailings

Purpose: The effectiveness of the Contractor to rapidly disseminate priority CTEP mailings will be measured.

Element: Timeliness

AQL: All priority mailings shall be sent out within two business days or less of receipt of complete document.

Incentives: Increase fee 1% if average time is one day or less.

Disincentives: Decrease fee 1% if average time is three calendar days. Decrease fee 2% if average time is four or more calendar days.

Method: Measured by reviewing the tracking log semiannually

Timing: On or about the 15th of the month following the half year reviewed.

Exceptions: none

Fee:

Base: 2%

Max: 3%

Business Rules:

Priority mailing definition: mailings that require a protocol or status change or are deemed a priority by CTEP. The Contractor

shall maintain a Priority Mailing Tracking Log which shall include (at minimum) the following information for each routine mailing: Agent or protocol number, mailing type, date request received in PIO, date sent and number of protocols affected. Base fee will be awarded when there are no priority mailings in the period being reviewed.

18. Timeliness: Scientific Writing Support

Purpose: The effectiveness of the Contractor to efficiently provide administrative support to assist CTEP Staff with protocol-related correspondence will be measured.

Element: Timeliness

AQL: Quarterly average time from receipt to return of document to CTEP requestor is two business days or less.

Incentives: Increase fee 1% if average time from receipt of request in PIO to return to requestor is less than two business days.

Disincentives: Decrease fee 1% if time from receipt of request in PIO to return to requestor is greater than three business days.

Method: Semiannual review of all Document Approval Forms submitted by CTEP staff.

Timing: On or about the 15th of the month following the half year reviewed.

Exceptions: none

Fee:

Base: 2%

Max: 3%

Business Rules:

The Contractor shall maintain a Document Tracking Log which shall include (at minimum) the following information for each request: CTEP requestor, date request received in PIO, date completed, cumulative score. Each writing request will count as one request, even if it has several iterations.

19. Timeliness: Amendment Submission to RAB

Purpose: The effectiveness of the Contractor to send protocol documents to Regulatory Affairs Branch for submission to the FDA will be measured.

Element: Timeliness

AQL: Quarterly average time from Document Approval to RAB receipt for FDA processing will be 30 calendar days or less.

Incentives: Increase fee 1% if average time is 15 calendar days or less.

Disincentives: Decrease fee 1% if AQL is not met.

Method: Measured by generating and reviewing a semiannual report

Timing: On or about the 15th of the month following the half year reviewed.

Exceptions: None.

Fee:

Base: 2%

Max: 3%

Business Rules:

The time sent to RAB shall be the date of the milestone "Sent to RAB" minus the amendment approval date as abstracted in PATS.

20. File Storage: Electronic Storage

Purpose: To assure rapid access by CTEP staff and contractors to documents.

AQL: 96% of complete documents saved electronically and linked to the PIO database (currently named PATS)

Incentives: Increase fee 1% if greater than or equal to 98%.

Disincentives: Decrease fee 1% for each 2% drop below AQL.

Method: Measured by generating and reviewing a semiannual report

Timing: On or about the 15th of the month following the half year reviewed.

Exceptions: Withdrawn or incomplete documents

Fee:

Base: 2%

Max: 3%

Business Rules:

All complete documents (PTMAs, Concepts, LOIs, Protocols, Revisions and Amendments) documents shall be saved and linked to the CTEP-ESYS.

21. Timeliness: Consensus Review Compilation

Purpose: The effectiveness of the Contractor to efficiently compile Consensus Reviews for protocols reviewed at PRC will be

measured.

Element: Timeliness

AQL: Semiannual average time from PRC to return of document to CTEP Lead Reviewer is three business days or less.

Incentives: None.

Disincentives: Decrease fee 1% if time from receipt of request in PIO to return to requestor is greater than three business days.

Method: Semiannual review of Document Tracking Log.

Timing: On or about the 15th of the month following the half year reviewed.

Exceptions: none

Fee:

Base: 1%

Max: 2%

Business Rules:

The Contractor shall maintain a Document Tracking Log which shall include (at minimum) the following information for each request: CTEP requestor, date request received in PIO, date completed. Each CR will count as one request, even if it has several iterations.

22. Quality: Internal Survey

Purpose: The Contractor shall assess overall quality of customer (CTEP staff) satisfaction.

Element: QA Activities

AQL: Average score of greater than or equal to 80%-90% on the QA survey.

Incentives: Increase fee 2% if average score is greater than or equal to 90%.

Disincentives: Decrease fee 2% for an average score of 70% to 79%. The Contractor will lose entire fee if average score is less than 70%.

Method: The Project Officer will review the annual QA survey.

Timing: On or about the 15th of the month following the completion of the annual survey.

Exceptions: none

Fee:

Base: 4%

Max: 6%

Business Rules:

The surveys shall be distributed to relevant NCI staff and/or NCI Contractor staff on a yearly basis.

23. Quality: External Survey

Purpose: To assess overall quality of customer (non-CTEP staff) satisfaction.

Element: QA Activities

AQL: Average score of greater than or equal to 80%-90% on the QA survey.

Incentives: Increase fee 2% if average score is greater than or equal to 90%.

Disincentives: Decrease fee 1.5% for an average score of 70% to 79%. The Contractor will lose entire fee if average score is less than 70%.

Method: The Project Officer will review the annual QA survey.

Timing: On or about the 15th of the month following the completion of the annual survey.

Exceptions: none

Fee:

Base: 3%

Max: 5%

Business Rules:

The surveys shall be distributed to groups of external collaborators on a yearly basis.

24. Trainings: Quantity

Purpose: The Contractor shall develop PIO related training programs for CTEP and/or extramural staff and contractors to assist CTEP Staff and extramural staff in the protocol development and review process.

Element: QA Activities

AQL: The Contractor shall develop and provide four PIO-related training programs per year.

Incentives: none

Disincentives: Decrease fee 1% for every training program not provided.

Method: Semiannual review of the training program log.

Timing: On or about the 15th of the month following the half year reviewed.

Exceptions: none

Fee:

Base: 2%

Max: 2%

Business Rules:

The Project Officer shall approve the topic, content, and format of all training programs. Each program shall include appropriate supporting documentation.

25. Trainings: Quality

Purpose: The Contractor shall develop PIO related training programs for CTEP and/or extramural staff and contractors to assist CTEP Staff and extramural staff in the protocol development and review process.

Element: QA Activities

AQL: Average score of greater than or equal to 80%-90% on the QA survey.

Incentives: Increase fee 1% if average score is greater than or equal to 90% for all training programs combined.

Disincentives: Decrease fee 0.5% for an average score of 70% to 79%. The Contractor will lose entire fee if average score is less than 70%.

Method: Semiannual review of the QA surveys for each training session

Timing: On or about the 15th of the month following the half year reviewed.

Exceptions: none

Fee:

Base: 1%

Max: 2%

Business Rules:

The Contractor shall deliver the program evaluations and summary for the period being reviewed to the Project.